

REMARKS

I. Amendments and Status of the Claims

The abstract has been amended to recite specific uses of the compounds of the present invention. The new language finds support, among other places, in the specification on page 4, lines 10-14.

Claims 1 and 3-9 are pending, with claim 1 being independent. Claims 1 and 7 have been amended, and claim 2 has been canceled, all without prejudice to pursue canceled subject matter in a continuation application, and without disclaimer of any subject matter. Claim 1 has been amended to recite only elected subject matter. Claim 7 has been amended to recite "anxiety disorders, depression, Parkinson's disease, and schizophrenia." Support for this amendment can be found, for example, in the specification at page 5, lines 5-9.

II. Abstract

The Examiner has requested that specific intended uses be identified in the abstract. Final Office Action at 2. Accordingly, Applicants have amended the abstract to include specific intended uses. Accordingly, this objection should be withdrawn.

III. Claim Rejections under 35 U.S.C. § 112

A. 35 U.S.C. § 112, ¶ 2

Claim 9 has been rejected under 35 U.S.C. § 112, ¶ 2 as allegedly being indefinite for failing to point out and distinctly claim subject matter that the Applicants

regard as their invention. Final Office Action at 2. The scope of diseases covered by this claim is allegedly unknown. *Id.*

Applicants respectfully contend that the scope of claim 9 is indeed definite. Applicants have discovered that the compounds set forth in claim 1 may have a high affinity for the dopamine D₂ receptor and the serotonin reuptake site. Specification at 4, lines 10-11. In addition, "some of the compounds having formula (I) show (partial) agonist activity at dopamine receptors making them particularly suitable for the treatment of Parkinson's disease." *Id.* at lines 16-18. In other words, Applicants have invented a means to interact with the dopamine and serotonin systems that has not been known before. It follows that Applicants should be allowed to protect that invention.

It is also known that interacting with certain molecular receptors can affect bodily systems. For example, it is known that inhibiting serotonin reuptake strengthens the functioning of the serotonergic system. It is also known that agonist activity at dopamine receptors can signal potential treatments for Parkinson's disease. See specification at 4, lines 16-18. Interacting with those molecular receptors has been demonstrated to treat disorders caused by disturbances in those systems. Accordingly, inventing a new means to interact with those systems deserves protection at least because it is useful.

The scope of claim 9 is clear to one of ordinary skill in the art. Claim 9 recites "A method of treating at least one central nervous system disorder . . . wherein the at least one central nervous system disorder is caused by a disturbance in the dopaminergic or serotonergic systems." The skilled artisan knows that the claim covers treating a CNS

disorder caused by a listed disturbance. The skilled artisan also knows that the claim does not cover a CNS disorder that is not caused by a listed disturbance. The scope of diseases covered by the claimed method is therefore clear. "Breadth of a claim is not to be equated with indefiniteness." M.P.E.P. § 2173.04 (*citing In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (C.C.P.A. 1971)). That the claim is merely broad, therefore, should not be grounds for rejection under 35 U.S.C. § 112, ¶ 2. Applicants respectfully request that this rejection be withdrawn.

B. 35 U.S.C. § 112, ¶ 1

Claims 7 and 9 have been rejected under 35 U.S.C. § 112, ¶ 1 for allegedly failing to comply with the enablement requirement. Final Office Action at 3. The Examiner contends that "the scope of uses still claimed remain nonenabled for reasons set forth previously." *Id.* Applicants allegedly have not enabled the scope of diseases recited in the claims, in spite of ample evidence of *in vitro* and animal testing presented in the specification. Allegedly, "[t]he animal models actually employed on instant compounds as reported in the specification are only for anxiety, depression, and Parkinson's." *Id.* Treatment of those disorders and schizophrenia are enabled, however. *See id.* Applicants respectfully disagree with this rejection.

A patent specification need not provide working examples. *See* M.P.E.P. § 2164.02. However, Applicants provide ample disclosure of working examples in the form of testing with *in vitro* and animal models. *See, for example*, specification at 4-5. In spite of that disclosure, the Examiner insists that the animal testing does not correlate with the scope of the treatments claimed. Final Office Action at 3-4. Applicants

disagree. Furthermore, the law does not require a strict correlation between testing and claimed uses:

A rigorous or an invariable exact correlation is not required, as stated in *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985):

[B]ased upon the relevant evidence as a whole, there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonably based on the probative evidence. (Citations omitted.)

M.P.E.P. 2164.02. That case discusses the correlation between *in vitro* and *in vivo* utility. Applicants show *in vitro* affinity for dopamine D₂ receptors and the serotonin reuptake site in the specification at 4, lines 10-11. Moreover, Applicants have shown *in vivo* activity in animal models for disorders caused by the dopaminergic and/or serotonergic systems. Applicants correlate that *in vitro* affinity and *in vivo* activity with therapeutic activity, and respectfully submit that there exists a reasonable correlation between the demonstrated activity and the therapeutic activity they claim.

Nonetheless, solely to advance prosecution, and without prejudice to pursuing canceled subject matter in a continuation application, Applicants have amended claim 7 to recite "anxiety disorders, depression, Parkinson's disease, and schizophrenia," disorders the Examiner identifies as enabled.

The rejection under 35 U.S.C. § 112, ¶ 1 should therefore be withdrawn as to both claims 7 and 9.

IV. Double Patenting Rejection

Claims 1-3, 5, and 7-9 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-3 of copending Application No. 10/432,225. Final Office Action at 4.

Without acquiescing to the merits of the rejection, Applicants file herewith a Terminal Disclaimer over co-pending Application No. 10/432,225. This rejection, therefore, should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Attachment: Terminal Disclaimer